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February 18, 2021

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VIA ECF

The Honorable Gregory H. Woods
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: *Skiadas v. Acer Therapeutics Inc. et al.*, No., 1:19-cv-06137 (S.D.N.Y.)

Dear Judge Woods:

Pursuant to Section 2.C of Your Honor's Individual Rules of Practice, and as directed at the January 21, 2021 Conference, Defendants request leave to move to dismiss the new claims in the Third Amended Class Action Complaint ("TAC").[1] The TAC adds claims about three categories of statements: (1) FDA's "additional guidance" at a May 2017 meeting, (2) statements about statistical significance and phenotype characteristics in the Ong Trial, and (3) Acer status updates (collectively, the "new" challenged statements). These new challenged statements are not false or misleading, and Plaintiff fails to adequately allege scienter with respect to them. The statements about the Ong Trial boil down to a non-actionable disagreement over interpretation of the data, while Acer's extensive risk disclosures and public knowledge of the Ong Trial's limitations belie any claim that Acer's statements were misleading.

I. Stating Truthfully That the FDA Provided Additional Guidance Was Not an Indication That Approval Was Guaranteed

In its 2017 10-K and a July 2018 prospectus, Defendants truthfully stated that during a May 2017 meeting, "the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing." Plaintiff alleges this somehow misled investors about the likelihood of and timeline for FDA approval. (TAC ¶¶ 166, 179.) This Court dismissed this *exact* statement and *exact* claim with prejudice in the SAC holding that "[n]o reasonable investor could interpret the statement . . . to mean that the FDA had indicated that the Ong Trial data were adequate to assure FDA approval of EDSIVO." (ECF No. 54 at 17-18.) Plaintiff revives this dismissed claim, asserting that the FDA raised concerns about randomization imbalance and interim analyses in the Ong Trial that "could not be remedied after-the-fact." (TAC ¶¶ 89, 167, and 180.) But Plaintiff's assertion is not contrary to Acer's statement about the guidance provided; the May 2017 Meeting Minutes show the FDA directed Acer to schedule additional meetings to discuss the "results of [the Ong Trial]" and "how the data will be presented in the NDA." (TAC Ex. 2 at ACER_0002339-40.) The FDA did not say Acer could not address the issues. Indeed, it would be illogical for the FDA to continue to meet with Acer and accept the

[1] Defendants do not seek to dismiss the claim relating to the three statements regarding the FDA's agreement about additional clinical studies, which previously survived dismissal of the Second Amended Complaint ("SAC"). (TAC ¶¶ 159-60, 164-65, 177-78.)

NDA submission for filing if the FDA had determined in May 2017 that Acer could not satisfy concerns regarding the Ong Trial. Nothing in the Minutes changes the Court's ruling dismissing the "guidance" claim and it should be dismissed again. *See Pettiford v. City of Yonkers,* No. 14 CIV. 6271 (JCM), 2020 WL 1989419, at *4 (S.D.N.Y. Apr. 27, 2020) (denying motion to reconsider denial of amendment, finding new evidence did not change the court's previous conclusion).

II. Acer's Statements Regarding the Ong Trial Were Not Misleading

First, the TAC takes issue with Acer's statements about the Ong Trial, but ignores that the trial *and* its limitations were published in a prominent peer-reviewed journal, *The Lancet*, and thus in the public domain, along with other public criticism,[2] long before the Complete Response Letter. And, Acer was not required to chronicle the two-plus years of back and forth with the FDA. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 541 (S.D.N.Y. 2015) ("[C]ourts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review.").

Second, statements that Ong Trial data was "robust" and "statistically significant" are non-actionable expressions of opinions.[3] *Id.* at 543-44. The Ong Trial publication showed statistically significant improvement in event free survival compared to control, "support[ing] Defendants' positive interpretation of the data, precluding a finding that Defendants' opinions were 'false' or 'not honestly believed when they were made.'" *In re EDAP Sec. Litig.*, 2015 WL 5326166, at *10 (S.D.N.Y. Sept. 14, 2015). Although the FDA ultimately interpreted the data using a different method, "Plaintiff[ ] cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial." *Id.*; *see Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (statement not misleading if Defendants "conducted a 'meaningful' inquiry and in fact held that view"). And, "[a]lthough the FDA had identified deficiencies in [the] data during the review process, the Complaint contains insufficient allegations to 'infer that it was a 'foregone conclusion' that . . . adverse consequences would ensue.'" *EDAP*, 2015 WL 5326166, at *11.

Third, Acer's statement about "important phenotype characteristics" in the Ong Trial (TAC ¶¶ 156, 162, 170, 175, and 186) were taken directly from *The Lancet*: "[I]mportant phenotype characteristics were equally balanced between celiprolol and control groups."[4] Acer relied on the Ong Trial analysis and was working to address FDA concerns throughout the review period.

Finally, if the FDA said concerns about the Ong Trial precluded approval, it would not have accepted Acer's NDA submission. Instead, as the TAC exhibits show, the FDA and Acer continued to discuss the Ong Trial as support for the NDA and the FDA reserved judgment for its final review decision.[5]

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[2] *E.g.*, *Pharmaceutical Technology* (Jan. 28, 2019), "Why the experts say Acer is unlikely to get FDA nod for vEDS drug," *available at* https://www.pharmaceutical-technology.com/comment/ehlers-danlos-syndrome-treatment/.

[3] *See* TAC ¶¶ 152, 155, 157, 169, 171, 172, 182, 183, 189, and 190.

[4] Kim-Thanh Ong et al., *Effect of celiprolol on prevention of cardiovascular events in vascular Ehlers-Danlos syndrome: a prospective randomised, open, blinded-endpoints trial*, 376 The Lancet 9751, at 1479 (Oct. 30, 2010).

[5] *See* Feb. 11, 2019 Mid-Cycle Communication (TAC Ex. 8) at ACER_0002652 ("[T]hese comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application.")

III. Statements About Acer Status Updates Are Not Actionable

Acer announced completion of a retrospective source verified analysis (TAC ¶ 152) and publication of the Paris Registry data (*id.* ¶ 196). The TAC's allegations about FDA communications do not affect the truth of these progress statements. And, Defendants' statements that confirmation of Ong Trial conclusions was a "critical element" of the NDA and "[w]e continue to successfully rapidly advance our lead product candidate" (*id.* ¶ 152) are non-actionable expressions of corporate optimism. *See Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 585 n.15 (S.D.N.Y. 2016).

IV. Plaintiff Fails To Allege Scienter, an Independent Basis for Dismissal

Plaintiff fails to allege a compelling inference of scienter as to the new challenged statements. *First*, there are no insider stock sales or other sufficient motive allegations and all money raised was invested in product development. *In re N. Telecom Ltd. Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("[a]bsence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders."). Plaintiff points instead to the need to raise money, which *alone* is not sufficient in this Circuit to support an inference of scienter. *See In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 532 (S.D.N.Y. 2009), *aff'd sub nom., Condra v. PXRE Grp. Ltd.*, 357 F. App'x 393 (2d Cir. 2009) (desire to "raise money that is 'desperately needed' or necessary 'to protect the very survival' of a company . . . is far too generalized (and generalizable) to allege the proper 'concrete and personal' benefit required by the Second Circuit."); *Kalnit v. Eichler,* 264 F.3d 131, 139 (2d Cir. 2001) ("[m]otives that are generally possessed by most corporate directors and officers do not suffice" to support a strong inference of scienter). *Second*, Plaintiff fails to allege strong circumstantial evidence that Defendants' "state of mind approximat[ed] actual intent" to relay false or misleading information. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015). Without motive, "the strength of the circumstantial [evidence] must be correspondingly greater." *Kalnit,* 264 F.3d at 142.

This Court previously found four factors supporting scienter in connection with the "FDA agreed" statements. *Skiadas v. Acer Therapeutics Inc.*, 2020 WL 3268495, at *10-12 (S.D.N.Y. June 16, 2020). Putting aside raising funds (discussed above), the other three factors—(1) implication that FDA agreed to approve with one study, (2) revisions to the challenged statement, and (3) access to allegedly contrary information (here, instead, the evidence shows Acer was engaged in a continuing dialogue with the FDA)—do not apply to the new challenged statements and thus there is not a strong, compelling inference of fraudulent intent. It cannot be that the FDA told Acer since May 2017 that Ong Trial issues precluded NDA approval, but still accepted the NDA for filing and priority review, and that Defendants withheld this information and continued to invest all of their time, money, and reputation on the NDA nonetheless. *See Shields v. Citytrust Bancorp, Inc*. 25 F.3d 1124, 1130 (2d Cir. 1994) ("[i]t is hard to see what benefits accrue from a short respite from an inevitable day of reckoning."). The more compelling inference is that Defendants "worked diligently to comply with FDA requirements and honestly believed that their diligence would lead to approval of their [ ] application." *EDAP*, 2015 WL 5326166, at *14. The exhibits to the TAC support this inference: Acer and the FDA engaged in a years-long dialogue regarding the Ong Trial—meeting multiple times, discussing the FDA's concerns, and providing additional information and over two dozen amendments in response to FDA questions.

V. Schedule

As the Court directed at the January 21, 2021 Conference, the parties met and conferred regarding a potential resolution and will be continuing those discussions. So that the parties can devote sufficient time and resources to continued discussions in an attempt to resolve this matter, the parties jointly request that the Court schedule Defendants' opening brief for June 1, 2021.

Respectfully submitted,

/s/ Jamie A. Levitt

Jamie A. Levitt

cc: All counsel of record (via ECF)